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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,611	10/10/2003	Dwayne Kirk	3121/2002	5103
29933 7590 10/18/2007 PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199				
			EXAMINER KUMAR, VINOD	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/683,611

Applicant(s)

KIRK ET AL.

Examiner

Vinod Kumar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/25/07 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/25/07</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Status of objections and rejections

1. Office acknowledges the receipt of Applicant's response filed on July 25, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 5-8, and newly added claims 70-72 are pending. Claims 5-8 and newly added claims 70-72 are examined on merits in the instant Office action. All previous objections to specification and drawings have been withdrawn in view of amendments to the specification and drawings. This action is made FINAL.

Election/Restriction

2. Applicants were reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

3. Claims 5-8 remain, and newly added claims 70-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Ooijen et al. (United States Patent No. 6,022,846, issued February 8, 2000) for the reasons of record stated in the Office action mailed on January 25, 2007, and taken with the evidence of Ullah et al. (Biochem. Biophys. Res. Commun. 306:603-609, 2003) and Mullaney et al. (Appl. Microbial. Biotechnol., 35:611-

614, 1991). Ullah et al. and Mullaney et al. are cited as references teaching the inherent property necessitated by the amendment. Applicants traverse the rejection in the paper filed on July 25, 2007.

Applicants argue that Office must provide rationale or evidence tending to show inherency. Applicants further argue that the instant specification describes numerous uses of the claimed stable dry homogenate of a transgenic plant expressing immunocontraception. Applicants further argue that Van Ooijen et al. fail to disclose that the instantly claimed product was made by the method recited in claim 5. Applicants further argue that that newly added claim 70 requires the addition of "Excipient" which is not disclosed in the reference (response, page 6, lines 7-9, 18-23; page 7, 7-28).

Applicant's arguments were fully considered but were not found to be persuasive. Applicants are reminded that an antigen is usually a protein molecule that stimulates an immune response, which involves production of antibodies. In the instant case, phytase protein disclosed in the reference is inherently associated with the property of an antigen because it can produce antibodies when injected into an animal, such as rabbit. In response to Applicant's arguments on inherency, Applicant's attention is drawn to Ullah et al. (see in particular, page 604, figure 1, and page 606, right column), and Mullaney et al. (see in particular, page 612, figure 1), wherein it is clearly disclosed that phytase (same as disclosed in the prior art) has antigenic property because said phytase could be detected by an immunoblot using antibodies raised against the antigen phytase.

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It is further maintained that the transgenic plant material derived animal feed disclosed in the reference inherently constitutes a pharmaceutical composition because the reference discloses that the transgenic plant comprising heterologous protein phytase improves the nutritional value of animal feed by efficiently utilizing phytate phosphorous present in the transgenic plant feed. The reference also discloses that animal feed comprising said transgenic material is used in industrial processes which requires action of transgenic phytase, wherein said industrial processes would inherently require addition of water, a pharmaceutically acceptable carrier.

In response to Applicant's argument over the limitation "excipient" in the newly added claim 70, it is noted that the specification does not provide a clear definition to the recitation "excipient". Page 19 of the specification gave examples but did not define the term. In view of this, Office is interpreting "excipient" as an inactive ingredient in a pharmaceutical composition to argue inherency. The instantly claimed stable dry homogenate of a transgenic plant would inherently comprise cellulose (plant cell wall material) as an "excipient".

Applicants are further reminded that the product by the reference may not be using the same method steps as the instantly claimed product. However, the instantly claimed product has the same structural limitations as that taught by the reference. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-

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by-process claim is the same as from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Applicants are also reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Accordingly, Van Ooijen et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ooijen et al. (United States Patent No. 6,022,846, issued February 8, 2000) in view of Schwoebel et al. (Journal of Biological Chemistry, 266:7214-7219, 1991) and Walmsley et al. (Current Opinion in Biotechnology, 11:126-129, 2000; Applicant's IDS filed 07/25/07).

Van Ooijen et al. teach a stable transgenic tobacco plant comprising expression of a heterologous protein phytase. The reference further teaches that said transgenic material is milled or ground to produce a stable feed meal for animals. See in particular, abstract, columns 1-2, 3-4, 9, Examples 6-14.

The transgenic plant material derived animal feed taught in the reference also constitutes a pharmaceutical composition because the reference teaches that the transgenic plant comprising heterologous protein phytase improves the nutritional value of animal feed by efficiently utilizing phytate phosphorous present in the transgenic plant feed. The reference also teaches that animal feed comprising said transgenic material is used in industrial processes which requires action of transgenic phytase, wherein said industrial processes requires addition of water (excipient), a pharmaceutically acceptable carrier. See in particular, 3rd paragraph of column 9.

Van Ooijen et al. do not teach expression of heterologous protein inducing immunocontraception.

Schwoebel et al. teach isolation of a cDNA (coding sequence) encoding an antigenic protein zona pellucida (ZP) from rabbit. The reference further teaches ZP antigenic protein can be used in the development of immunocontraceptive vaccines. See in particular, page 7214, abstract, 2nd paragraph of right column; page 7215, materials and method; page 7216, figures 1 and 2; page 7217; figures 3-5.

Walmsley et al. teach transgenic plants expressing heterologous protein of interest which can be used for delivering edible vaccines. The reference clearly teaches advantages of producing vaccines in plants, such as, elimination of the risk of contamination with animal pathogens, provides a heat-stable environment, and enables oral delivery, and thus eliminating injection-related hazards. See the entire article, and in particular introduction in left column of page 126.

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At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to modify the method of making a stable dry homogenate of a transgenic plant as taught by Van Ooijen et al., to substitute the coding sequence encoding phytase of Van Ooijen et al. with Schwoebel et al. coding sequence encoding an antigenic zona pellucida protein to obtain a stable dry homogenate of a transgenic plant comprising high levels of heterologous zona pellucida protein.

Given that Schwoebel et al. teach that zona pellucida proteins could be used for the development of immunocontraceptive vaccine, and Walmsley et al. teach advantages of delivering edible vaccines in animals, one of ordinary skill in the art would have been motivated at the time the claimed invention was made to use the dry homogenate derived from a transgenic plant expressing high levels of zona pellucida protein as an edible vaccine to control population of pest animals with reasonable expectation of success.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

This rejection has been necessitated due to the claim amendment filed in the paper of July 25, 2007.

Summary

5. Claims 5-8 remain, and newly added claims 70-72 are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is set to expire within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

